UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/027,654	02/23/98	HORTON J	28911/34561

HM12/0522

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EXAMINER	
GABEL, G	
ART UNIT	**PAPER NUMBER**
1641	13

DATE MAILED: 05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/027,654	HORTON, JEFFREY KENNETH	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 3/9/01 in Paper No. 12 is acknowledged and has been entered. Claims 17 and 18 have been amended. Currently, Claims 1-2, and 4-18 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-2 and 4-20 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, is incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Specifically, it is unclear what structural and functional cooperative relationships exist between the elements or absence thereof (assay reagents, i.e. tracer / label) in claim 1 and the claimed "assay reagents" in the subsequent claims 17 and 18. Specifically, it is unclear how detection is effected in the absence of a label or a tracer.

Claim 17 is vague and indefinite in reciting "reaction mixture comprises a tracer" because it fails to specifically define how the "tracer" structurally relates to the reaction mixture in claim 1.

Claim 18 is vague and indefinite in reciting "reaction mixture comprises a labeled reagent" because it fails to specifically define how the "labeled reagent" structurally relates to the reaction mixture in claim 1. Further, it is unclear what is encompassed by the term "reagent" in relation to the reaction mixture.

As pointed out by Applicant in page 4 of the amendment or at page 14 of the specification, the "the tracer is a labeled assay reagent which might be the specific binding partner of the analyte...". In Example 5, $^{3}HIP_3$ is a tracer in competition with unlabeled IP_3. At page 5, line 26 of the specification, "enzymes are the most widely used tracers ...". It is therefore suggested but not required for definiteness and clarity of claim 1 to recite:

"ii) mixing the lysed cellular sample with a specific binding assay reagent comprising a specific binding partner of the analyte and a tracer (or label) to form a reaction mixture comprising a specific binding partner-analyte complex."

It then follows that claims 17 and 18 can be maintained as recited in Paper no. 7, minimally clarifying claim 18 as "the assay reagents comprise a label for detection wherein the label is selected from the group ..."

Responsive to applicant's argument that the claims are clear in light of the specification, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 4-5, 8-11, and 13-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cook (1) (Research Focus, 1996) in view of Lundin (US 5,558,986) for reason of record.

4. Claims 6-7 and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cook (1) (Research Focus, 1996) in view of Lundin (US 5,558,986), and in further view of Cook (2) (WO 94/26413) for reason of record.

Response to Arguments

5. A) Applicant argues that Cook (1) does not disclose use of SPA or specific binders with a detergent to provide lysed cellular samples and does not provide indication as to whether such an approach would be successful or pose a problem.

In response, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In*

re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, while Cook (1) did not address issues such as lysing using a detergent and neutralizing the detergent using a sequestrant in a homogeneous assay wherein no separation of elements is required, Cook (1) provides a motivation or suggestion to make more accessible, intracellular analytes such as prostaglandins and interleukins, whose presence represent cellular biochemical activity. Lundin, on the other hand, disclose the use of a detergent in lysing cellular samples for the purpose of extracting analytes from cellular samples and further the use of cyclodextrin in neutralizing its effects on specific binding partners and suggested such procedure in general assay applications including the homogeneous SPA assay taught by Cook (1) or enzyme assays (column 7, lines 28-38).

B) Applicant argues that an affirmative choice to combine both the teachings of Cook (1) and Lundin even in the presence of the elements taught by Lundin, is not an obvious straightforward choice in relation to Applicant's invention.

In response, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

C) Applicant argues that those of skill in the art would not have attempted a specific binding assay using a complexing agent as strong as the cyclodextrin sequestrant taught by Lundin.

In response, the rejected claims do not exclude use of strong cyclodextrin sequestrants. Alternatively, Lundin taught that "if an apparent inhibition is found in any other assay (from enzyme assays)" optimising concentrations of binding partners in reaction mixtures (cofactors) in the presence of cyclodextrin (inhibitory effects) is suggested; thus providing motivation to optimise concentrations in reaction mixtures such as recited in the claimed invention (claim 4).

6. Applicant's amendment and arguments have been considered but are not deemed persuasive. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

5/17/01

Gail Gabel
Patent Examiner
Group 1641

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
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